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EXAMINER

BAXTER, ZOE E

ART UNIT	PAPER NUMBER
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3735

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/658,209	Applicant(s) GINSBERG, BARRY H.	
	Examiner Zoe E. Baxter	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 13-15, 22-30, 34, 43-48, 51-53, 60-65 and 71 is/are rejected.
- 7) ☒ Claim(s) 10-12, 16-21, 31-33, 35-42, 49, 50, 54-59 and 66-70 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to because figures 2, 5, 6 and 7 comprise lines, letters and numbers not uniformly thick and well defined, clean, durable and black (37 CFR 1.84(i)). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-5, 8-10, 12-15, 22-26, 29-31, 33, 34, 43-46, 49, 51-53, 60, 63-65 and 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Allen, III (U.S. Patent No. 4731726). Allen, III discloses a method of annunciating a patient's medical data levels using a medical data level monitoring device comprising the steps of storing medical data levels (column 4 line 52) with the corresponding dates and times of day the respective medical data levels were taken (column 10 line 51), calculating an average from at least a first medical data level and a second medical data level selected from the stored medical data levels, annunciating said average data level (column 3 lines 54-55), receiving a first user input to annunciate said first medical data level, annunciating said first medical data level, receiving a second user input to annunciate said second medical data level, annunciating said second medical data level (column 3 lines 54-56). Allen, III further describes the ability of the user to review the previous data using the RD key and scrolling through the two previous days data using a user input of a arrow key and annunciating the data from the previous day (column 10 lines 32-60).

4. Referring to claim 2 Allen, III discloses a method 33 wherein each of the three annunciating steps for annunciating the average medical data level, the first medical data level and second medical data level can be performed by one of displaying on a display device (column 3 lines 54-57) and generating an audible sound via a speaker (column 4 lines 61-62).

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5. Referring to claim 3 Allen, III discloses the medical data levels are blood glucose levels (column 1 lines 50-51) and the monitoring device is a blood glucose monitor (column 1 lines 53-55).

6. Referring to claim 4 Allen, III discloses a method comprising the steps of receiving a third user input to annunciate a value and annunciating the average medical data (column 2 lines 28-37).

7. Referring to claim 5 Allen, III discloses a method wherein the average medical data level calculation uses n stored medical data levels and n is an integer greater than 2 and n medical data levels comprise first medical data level and second medical data level (column 2 lines 28-37).

8. Referring to claim 8 Allen, III discloses a method where stored medical levels are constituent values of the average medical data level comprising the steps of receiving a user input after the first and second medical data level annunciating the next medical data level and repeat the receiving step for another user input to annunciate the next medical data level. Allen III explains that the user can perform a scheduled or unscheduled blood test after each test the monitor automatically provides a 3-day average for the relative time of day (column 3 lines 54-57).

9. Referring to claim 9 Allen, III discloses a method in which after each blood test the monitor automatically provides the previous 3-day blood sugar average (column 3 lines 54-56).

10. Referring to claim 13 Allen, III discloses a method of defining the time of day for a time period of a selected number of days (column 3 lines 54-56).

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11. Referring to claim 14 Allen, III discloses defining the time period during the day as a relative time of day for instance a time relative to a meal (column 8 lines 40-47). The average is taken over a three-day period for comparable time periods (column 3 lines 54-56).

12. Referring to claim 15 Allen, III defines the number of days as being the previous three days (column 3 lines 54-56).

13. Referring to claim 22 Allen, III discloses an apparatus comprising a reader (column 5 lines 1-3), a memory device (column 4 lines 51-53), an annunciator (column 3 line 44), a user input device (column 3 lines 45-46) and a processing device connected to the reader, memory device, annunciator, and input device programmable to calculate an average medical data level from the stored medical data level from at least a first and second medical data level selected from the stored medical data levels, annunciate the average medical data via the annunciator, receive a first user input from the user input device to annunciate the first medical data level, to annunciate the first medical data level, annunciate the first medical data level in response to said first user input, to receive a second user input from the user input device to annunciate the second medical data level, and to annunciate the second medical data level in response to the second user input (column 4 lines 51-63).

14. Referring to claim 23 Allen, III teaches an apparatus wherein the annunciator is at least one of a display device (column 3 line 44) and a speaker (column 4 line 61) and processing device is operable to annunciate by one of displaying on the display (column 7 lines 64-65) and generate an audible sound via the speaker (column 4 lines 61-63).

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15. Referring to claim 24 Allen, III teaches an apparatus wherein the medical data levels are blood glucose levels (column 1 line 51) and the apparatus is a blood glucose meter (column 2 lines 28-31).

16. Referring to claim 25 Allen, III teaches an apparatus wherein the processing device is programmable to receive a third user input, to annunciate a value and to annunciate the average medical data level (column 3 lines 54-56). If the apparatus is able to produce a 3-day average the apparatus has to be able to process three user inputs.

17. Referring to claim 26 Allen, III teaches an apparatus wherein the processing device is programmable to receive a third user input, to annunciate a value and to annunciate the average medical data level (column 3 lines 54-56). If the apparatus is able to produce a 3-day average the apparatus has to be able to process three user inputs. Three is an integer greater than two.

18. Referring to claim 29 Allen, III teaches an apparatus wherein the n stored medical data levels are constituent values of the average medical data level and the processing device is further programmable to receive another user input to annunciate the next medical data level among the n medical data levels, to annunciate the next medical data level and repeat the operations of receiving another user input to annunciate the next medical data level among the n medical data levels and annunciating the next medical data level until each of the constituent values has been annunciated (column 8 lines 47-57).

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19. Referring to claim 30 Allen, III teaches an apparatus wherein the processing device is programmable to annunciate the average medical data level after the last medical data level has been annunciated (column 3 lines 54-56).

20. Referring to claim 34 Allen, III teaches the processing device is operable to select stored medical data levels used to determine the average medical data level based on the date and time of day the stored medical data levels were taken (column 8 lines 40-47).

21. Referring to claim 43 Allen, III teaches an apparatus wherein the user input device comprises forward and backward arrow keys for navigation forward and backward among the annunciated constituent values (column 4 lines 28-31).

22. Referring to claim 44 Allen, III teaches a method of displaying blood glucose levels using a blood glucose meter comprising the steps of storing blood glucose levels with the corresponding dates and times of day the respective blood glucose levels were taken (column 8 lines 37-57), calculating an average blood glucose from at least three of the stored blood glucose level as the constituent values (column 3 lines 54-56), displaying the average blood glucose level using a display device of blood glucose meter (column 3 lines 54-56), receiving a first user input to display a first one of the constituent values, displaying the first one of the constituent values in response to the first user input, receiving a second user input to display a second one of the constituent values in response to the second user input (column 8 lines 37-57).

23. Referring to claim 45 Allen, III teaches a method in which he uses a three day average in order to produce a three day average of blood glucose the method must comprise receiving a third user input to display the third constituent value, displaying the

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third constituent value (column 3 lines 54-56) and displaying the average blood glucose levels each time an additional glucose level is input (column 2 lines 54-56).

24. Referring to claim 46 Allen, III teaches a blood glucose meter comprising a forward and backward arrow key for navigation among the different displayed constituent values (column 4 lines 28-31).

25. Referring to claim 51 Allen, III teaches a method of calculating step comprising the step of selecting the stored blood glucose levels used to determine the average blood glucose level based on the date and time of day the stored blood glucose levels were taken (column 3 lines 54-56).

26. Referring to claim 52 Allen, III teaches a method of calculating an average comprising defining a time period during a day (column 8 lines 44-47) when the average blood glucose level is desired for that time period on each of the selected number of days (column 3 lines 54-56).

27. Referring to claim 53 Allen, III discloses a method in which an average is taken over a number of days; the number of days the average is taken is three days (column 3 lines 54-56).

28. Referring to claim 60 Allen, III discloses a method of displaying a blood glucose levels using a blood glucose meter comprising the steps of storing blood glucose levels with the corresponding dates and times of day the respective blood glucose levels were taken (column 8 lines 37-57), calculating an average blood glucose level from at least three of the stored blood glucose levels as the constituent values (column 3 lines 54-56), displaying the average blood glucose level using a display device of the blood glucose meter (column 3 lines 54-56) and displaying the constituent values at least one

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of substantially simultaneously with the average blood glucose level, and sequentially displaying screens for respective ones of the average blood glucose level and the constituent values that can be generated in a round robin manner (column 3 lines 56-57).

29. Referring to claim 63 Allen, III discloses a method of calculating an average blood glucose level used to determine the average blood glucose level based on the date and time of day the stored blood glucose levels were taken (column 3 lines 54-56).

30. Referring to claim 64 Allen, III discloses a method of calculating an average blood glucose level comprising the step of defining a time period during a day when the average blood glucose level is desired for that time period on each of the selected number of days (column 8 lines 44-47).

31. Referring to claim 65 Allen, III discloses a method in which the average blood glucose level is taken over a three-day period (column 3 lines 54-56).

32. Referring to claim 71 Allen, III discloses a method wherein the n time periods can comprise any of a breakfast mealtime, lunch mealtime, dinner mealtime, nighttime snack and other times (column 13 lines 15-32).

Claim Rejections - 35 USC § 103

33. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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34. Claims 6, 7, 27, 28, 47, 48, 61 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen, III in view of Kahn et al. (U.S. Patent No. 5251126).

Allen, III teaches a method wherein an average medical data level is calculated from more than two medical data levels. Allen, III does not teach announcing a variability indicator that indicates the variability between the n stored medical data levels. Kahn et al. teaches the method of using variability as an indicator of a medical data level (column 3 lines 34-35). It would have been obvious to one of ordinary skill in the art to modify the invention of Allen, III to include announcing a variability indicator similar to that of Kahn et al. in order to indicate statistically significant changes in the blood glucose level (Kahn et al. column 3 lines 30-35).

35. Referring to claim 7 Allen, III teaches a method wherein an average medical data level is calculated from more than two medical data levels. Allen, III does not teach using standard deviation as a measure of variability. Kahn et al. teaches the use of standard deviation as a measure of statistically significant change (column 3 lines 34-38). It would have been obvious to one of ordinary skill in the art to modify the invention of Allen, III to include standard deviation similar to that of Kahn et al. in order to track statistically significant changes in the blood glucose level (Kahn et al. column 3 lines 34-38).

36. Referring to claim 27 Allen, III teaches an apparatus wherein an average medical data level is calculated from more than two medical data levels. Allen, III does not teach announcing a variability indicator that indicates the variability between the n stored medical data levels. Kahn et al. teaches the method of using variability as an indicator of a medical data level (column 3 lines 34-35). It would have been obvious to

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one of ordinary skill in the art to modify the invention of Allen, III to include variability as an indicator similar to that of Kahn et al. in order to indicate statistically significant changes in the blood glucose (Kahn et al. column 3 lines 30-35).

37. Referring to claim 28 Allen, III teaches an apparatus wherein an average medical data level is calculated from more than two medical data levels. Allen, III does not teach using standard deviation as a measure of variability. Kahn et al. teaches the use of standard deviation as a measure of statistically significant change (column 3 lines 34-38). It would have been obvious to one of ordinary skill in the art to modify the invention of Allen, III to include standard deviation similar to that of Kahn et al. in order to indicate statistically significant changes (Kahn et al. column 3 lines 34-38).

38. Referring to claim 47 Allen, III teaches a method wherein an average medical data level is calculated from more than two medical data levels. Allen, III does not teach displaying a variability indicator that indicates the variability between the n stored blood glucose levels. Kahn et al. teaches the method of using variability as an indicator of a medical data level (column 3 lines 34-35). It would have been obvious to one of ordinary skill in the art to modify the invention of Allen, III to include displaying a variability indicator similar to that of Kahn et al. in order to indicate statistically significant changes (Kahn et al. column 3 lines 30-35).

39. Referring to claim 48 Allen, III teaches a method wherein an average medical data level is calculated from more than two medical data levels. Allen, III does not teach using standard deviation as a measure of variability. Kahn et al. teaches the use of standard deviation as a measure of statistically significant change (column 3 lines 34-38). It would have been obvious to one of ordinary skill in the art to modify the invention

of Allen, III to include the use of standard deviation similar to that of Kahn et al. in order to measure statistically significant change (Kahn et al. column 3 lines 34-38).

40. Referring to claim 61 Allen, III teaches a method wherein an average medical data level is calculated from more than two medical data levels. Allen, III does not teach displaying a variability indicator that indicates the variability between the n stored blood glucose levels. Kahn et al. teaches the method of using variability as an indicator of a medical data level (column 3 lines 34-35). It would have been obvious to one of ordinary skill in the art to modify the invention of Allen, III to include a variability indicator similar to that of Kahn et al. in order to indicate statistically significant change (Kahn et al. column 3 lines 30-35).

41. Referring to claim 62 Allen, III teaches a method wherein an average medical data level is calculated from more than two medical data levels. Allen, III does not teach using standard deviation as a measure of variability. Kahn et al. teaches the use of standard deviation as a measure of statistically significant change (column 3 lines 34-38). It would have been obvious to one of ordinary skill in the art to modify the invention of Allen, III to include standard deviation similar to that of Kahn et al. in order to measure statistically significant change (Kahn et al. column 3 lines 34-38).

Response to Arguments

42. Applicant's arguments filed 11/13/06 have been fully considered but they are not persuasive.

43. Referring to claims 1, 22, 40 and 60 applicants argues that Allen, III fails to display the constituents of the average following a user input, that Allen, III merely

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retrieves the medical data for the entire day. Allen, III discloses that after each blood test the monitor will automatically provide an average of the past three days. The Applicant does not specify in the claim that the average is taken from consecutive data merely that an average is taken from at least two medical data levels. The Applicant argues that the constituent levels are not being displayed in that Allen, III states when the user presses the RD button a days worth of medical data is being displayed.

Examiner wishes to point out that by displaying the entire day's worth of data the constituents from the previous day are also being displayed (column 3 lines 54-56).

The claim does not state that only a single medical data level is being displayed merely a medical data level. Allen, III is displaying multiple medical data levels including the constituent of the average.

44. Regarding the argument that Allen, III fails to teach or disclose a round robin display of an average and constituents as declared in claims 4, 8, 9, 25, 29, 30 and 45. Allen, III does state that upon a new test the average is automatically provided and upon user input the days constituents are displayed. By displaying the entire days constituents the constituents included in the average are also being displayed. It is not stated in the claims that the constituents are individually displayed.

45. Regarding the argument that Kahn et al. fail to teach a variability indicator as and Kahn et al fail to teach a round robin approach as to an average and constituents being displayed as claimed in claims 6, 7, 27, 28, 47, 48, 61 and 62 it is again pointed out that Allen, III does teach the constituent levels of the above claims. Kahn et al. is being relied upon as teach the variability and specifically standard deviation (column 15 lines 11-23). Allen, III teaches the average among stored medical data as well as Kahn et al.

(figure 6). It is well known to one of ordinary skill in the art that variability can be shown through standard deviation. Kahn et al. in fact does teach the determination of an average and standard deviation among medical data levels (figure 6). Kahn et al. further discuss the mean and standard deviation of medical data levels in column 15 lines 11-23.

46. Applicant's arguments, see page 5 lines 19-23, filed November 13, 2006, with respect to a display having a first area for displaying an average and constituent values have been fully considered and are persuasive. The rejection of claims 10, 12, 31, 33 and 49 has been withdrawn. Prior art of record fail to teach or fairly suggest a display comprising a first area for displaying an average and its constituents and a second area for displaying indicators corresponding to medical data levels.

47. Applicant's arguments, see page 6 paragraph II, filed November 13, 2006, with respect to prompts annunciated to a user to define a time period when the average is desired for a selected number of days have been fully considered and are persuasive. The rejection of claims 35 and 36 has been withdrawn. Prior art of record fail to teach or fairly suggest a blood glucose monitor in which the user is able to define the time period when the average medical data is being taken.

Allowable Subject Matter

48. Claims 10-12, 16-21, 31-33, 35-42, 50, 49, 54-59, 66-70 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 10-12, 31-33, 49 and 50 all define over prior art because prior art fails to

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disclose a display comprising a first area for displaying an average and its constituents and a second area for displaying indicators corresponding to medical data levels.

49. Claims 16-21, 35-42, 54-59 and 66-70 define over the prior art because prior art fails to disclose a method in which the user is able to request an average medical data level for a selected number of days at a desired time period.

Conclusion

50. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

51. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

52. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zoe E. Baxter whose telephone number is 571-272-8964. The examiner can normally be reached on Monday-Friday 7:30am-4:00pm.

53. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

54. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Charles A. Marmor, II
Supervisory Patent Examiner
Art Unit 3735

ZEB